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TITLE: Prevention of Low Back Pain in the Military: A Randomized Clinical Trial

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14. ABSTRACT The second year of the Prevention of Low Back Pain in the Military (POLM) clinical trial was extremely successful. The research team was able to complete all Year 2 tasks in a timely fashion, and continues to work ahead in several areas. Study recruitment was completed in Year 2, with immediate follow-ups continuing to Year 3. This year the first publication from the POLM study was reported in the peer review literature and the first presentation was completed at a national conference. Long term follow up were started in Year 2, using the study specific website (https://polm.ufl.edu) as the platform for data collection and will continue in last 2 years of the study.					
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INTRODUCTION

Low back pain (LBP) is a musculoskeletal condition that accounts for significant pain and disability, and consumes substantial medical and occupational costs annually. Specific to the United States Armed Forces, LBP was the second most common reason to seek healthcare and affects over 150,000 active duty Soldiers annually (MSMR 2003). Soldiers in the U.S. Army with LBP have the highest risk of disability 5 years after their injury. Furthermore, a military review suggests that LBP was the most common condition bringing about a medical board, with lifetime direct compensation costs estimated to reach into the billions of dollars. Therefore, reduction of disability from LBP is a significant research priority for the military.

Reduction of disability from LBP has been divided into 2 separate phases – primary and secondary prevention. Primary prevention refers to interventions and strategies that are implemented before a low back injury occurs.² Primary prevention reduces LBP related disability by reducing the total number of people who eventually experience an episode of LBP. Secondary prevention refers to interventions and strategies that are implemented during the acute episode of low back injury, before chronic symptoms occur.¹ Secondary prevention reduces LBP related disability by reducing the number of people who eventually experience chronic disability from LBP. We are proposing an innovative approach to LBP prevention by combining primary and secondary prevention strategies that have the potential to limit the development of chronic LBP in Soldiers.

Objective/Hypothesis

The purpose of the Prevention of Low Back Pain in the Military (POLM) trial is to determine if a combined prevention program is more effective at limiting the development of chronic LBP when compared to the effects of individual evidence-based prevention programs, or a traditional exercise program.

Specific Aims

Specific Aim 1: We will determine if a combined prevention program consisting of core stabilization exercise program (CSEP) and psychosocial educational program (PSEP) prevents the development of chronic LBP. During advanced individual training (AIT), United States Army Soldiers who volunteer will be randomly assigned to receive 1 of 4 prevention programs. Soldiers will be followed monthly during the first 2 years following AIT to measure LBP occurrence and severity with a web-based data collection system managed at the University of Florida.

Specific Aim 2: We will determine if the CSEP results in favorable changes in specific core musculature associated with reducing LBP. The CSEP activates specific core musculature that is important in preventing LBP. We will use real-time ultrasound imaging to measure changes in core musculature that occur during AIT. We will also determine if the PSEP results in a favorable change in LBP beliefs. The PSEP educates individuals in an evidence-based, psychosocial approach to the management of LBP, which can potentially decrease the likelihood of experiencing chronic LBP. We will use a validated self-report questionnaire to measure Soldiers' LBP beliefs regarding outcome and management. We will measure LBP beliefs at the beginning and end of AIT (a 12-week period).

Relevance: The results of this study will have several immediate applications for Soldiers. The widespread incorporation of effective preventative strategies will certainly result in a substantial reduction of LBP in the military. Programs that effectively prevent the occurrence and severity of LBP would benefit the U.S. Armed Forces by improving the readiness of their Soldiers, reducing economic burden, and limiting disability among Soldiers. For example, an average

cost of \$136.02 per LBP visit was calculated for 2004. A 40% reduction in the recurrence of LBP after completing the CSEP would generate a cost savings of \$3,343,230 by the 4th fiscal year (approximately 1/5 of the total cost of LBP for one FY).

Low back pain prevention programs are necessary to reduce the impact of musculoskeletal injury in the United States Military. Low back injuries are a significant cause of disability in the United States Army. For example in the United States Military, LBP was the second most common reason to seek healthcare and affected over 150,000 active duty Soldiers. Soldiers in the United States Army with LBP have the highest risk of disability 5 years after injury and a review suggests that LBP was the most common condition bringing about a medical board, with lifetime direct compensation costs estimated to reach into the billions of dollars. Clearly, quality clinical research producing evidence related to LBP prevention is warranted for the United States Military.

Programs that effectively prevent the occurrence and severity of LBP would benefit the United States Military by improving the readiness of their Soldiers, reducing economic burden, and limiting disability among Soldiers.

BODY

As outlined in our SOW, Year 2 was dedicated to recruitment and collection of immediate follow-up data. These tasks are outlined below:

Task 2: Subject recruitment (Years 2 – 3)

- Obtain informed consent from Soldiers
- Collect pre-training measures
 - Self-report measures
 - Measures of mental and physical function
 - Negative affect
 - LBP
 - Muscle function measures
 - Multifidi
 - Transversus abdominus
 - Erector spinae
- Implement randomization scheme

Task 3: Data management and follow-up (Years 2 – 4)

- Collect onsite post-training measures (ongoing)
 - Self-report measures
 - Measures of mental and physical function
 - Negative affect
 - LBP
 - Muscle function measures (ongoing)
 - Multifidi
 - Transversus abdominus
 - Erector spinae
- Monitor for episodes of LBP through website (ongoing)
 - Soldier access through username and password
 - Complete episode questionnaire
 - Complete pain questionnaires
 - Complete beliefs and coping questionnaires
 - Monthly email to AKO email address to update profile
 - Complete episode questionnaire
 - Complete pain questionnaires
 - Complete beliefs and coping questionnaires
- Update and maintain web-based data management system (ongoing)
 - System checks and fixes
 - Error checks and fixes

All of these activities were completed in Year 2, with details outlined below:

- Recruitment completed on April 8, 2008 with 20 companies recruited (n = 4325) entered into the study, meeting initial sample size estimates.
- Immediate, onsite pre-training measures completed (n = 4325)
 - Self report measures
 - Muscle function measures
- Immediate, onsite post-training measures ongoing, with 18/20 companies (n = 2971)
 - Self report measures
 - Muscle function measures

- Subsequent episodes of LBP monitored via POLM website
 - Monthly emails sent (100% compliance)
 - Soldier follow-up responses low (10-20% response rate)
- Web-site and database management continued

In addition to Tasks specific to Year 2, the following recurring Tasks occurred in Year 2:

Task 5: Complete quarterly procedures (Years 1 – 4)

(NOTE: Task 5 will be completed once per quarter)

- Conference call between all investigators
- Prepare quarterly reports
 - Manual of Operations
 - Monitor human subjects and safety monitoring

Task 6: Complete annual procedures (Years 1 – 4)

(NOTE: Task 5 will be completed once per year)

- On-site meeting between principal investigators
- Prepare annual reports
 - Manual of Operations
 - Human subjects and safety monitoring
- Renew institutional human subjects approval

These activities were completed in Year 2, with details outlined below:

- Communication Between Investigators
 - Use of shared on-line calendar
 - Weekly conference calls
- On-Site Investigator Meeting
 - Steven George visited Texas site in June for long term follow up plans
- Institutional Review
 - BAMC human subject approval has been maintained continuously since February 2006, with appropriate modifications made as needed
 - University of Florida human subject approval has been maintained continuously since June 2006
 - USAMRMC HSRRB deferred review to BAMC June 2006.

Tasks scheduled for Year 3 of the SOW were initiated ahead of schedule in Year 2. These tasks are mentioned below.

Task 4: Dissemination of research findings (Years 3 - 4)

- Analyze and report pre-training findings (Year 3)
 - Scientific meeting (poster or platform presentation)
 - Manuscript submission
- Analyze and report post-training findings (Year 3)
 - Scientific meeting (poster or platform presentation)
 - Manuscript submission

Manuscripts were prepared from these data and are in review with *Medicine & Science in Sports & Exercise, Spine, and American Journal of Epidemiology*.

Core Stabilization Exercise Program Analysis (in review *Med Sci Sports Exerc*)

Despite longstanding tradition and widespread popularity of performing traditional sit-ups in the US Army, it has been postulated that this exercise results in increased lumbar spine loading, potentially increasing the risk of injury and development of low back pain (LBP). To address these potential concerns, health and fitness professionals commonly recommend performing “core stabilization” exercises, which have been shown to improve abdominal and trunk muscle strength without the excessive loading incurred with traditional sit-ups, based on evidence that suggests core stabilization exercises may decrease the incidence of LBP and increase performance. However, core stabilization exercise programs (CSEP) have not been widely adopted in the US Army because of the perceived deleterious impact that failure to pass the Army Physical Fitness Test (APFT), which includes traditional sit-ups, can have on the Soldier’s career. Therefore, the purpose of this study was to determine whether performing core stabilization exercises in lieu of traditional sit-ups would have detrimental effects on overall and sit-up scores and passing rates on the APFT.

Subjects included healthy Soldiers between 18-35 years of age (or 17 year old emancipated minor) participating in Advanced Individual Training (N=2616) at Fort Sam Houston in San Antonio, TX. Soldiers with a previous history of LBP or other serious condition that precluded participation in physical training were excluded. History of LBP was defined as having met each of the following: 1) limited work or physical activity, 2) duration > 48 hours, and 3) resulted in seeking of medical care.

Companies of Soldiers who were eligible and consented to the study were randomized to receive TEP with sit-ups or CSEP. A cluster randomization strategy was utilized for assigning companies to receive or not receive the CSEP since military training environments require living in close quarters with other members of the unit, making individual randomization unfeasible due to concerns related to disruption of normal training schedule and treatment contamination. Dependent measures were overall and sit-up scores and passing rates on the APFT. We performed a 2x4x2 repeated-measures ANOVA with pairwise comparisons using the Bonferroni inequality to examine differences in the overall and sit-up scores on the APFT. Differences in overall and sit-up passing rates were assessed with a chi-square. The alpha-level was set to .05 a priori. Numbers needed to treat were assessed to determine the potential impact on decision-making.

The mean age of participants was 21.9 ± 4.3 years of age (range: 17-35). Both groups performed sit-ups outside of unit physical training at equal rates (TEP: 69.5% and CSEP: 65%, $P=0.067$). There were no significant between group differences in overall scores ($P=0.142$) or sit-up performance ($P=0.543$) on the APFT after 12 weeks of training. CSEP and TEP improved their sit-up pass rates by 5.6% and 3.9%, respectively ($P<.05$). The NNT for CSEP was 56. Both groups demonstrated significant improvements in their overall and sit-up score and passing rates over time ($P<0.05$).

In summary, CSEP did not have a detrimental impact on APFT scores or passing rates. There was actually a small but significantly greater increase in sit-up pass rate in the CSEP (5.6%) versus the TEP (3.9%). Therefore, incorporating CSEP into Army physical training does not increase the risk of suboptimal performance on the APFT. A company with 400 Soldiers performing CSEP would actually result in 7 additional Soldiers progressing from a failure to a pass on the sit-up component of the APFT compared to TEP. The results of this study help to inform the development of optimal training programs for Army physical fitness training.

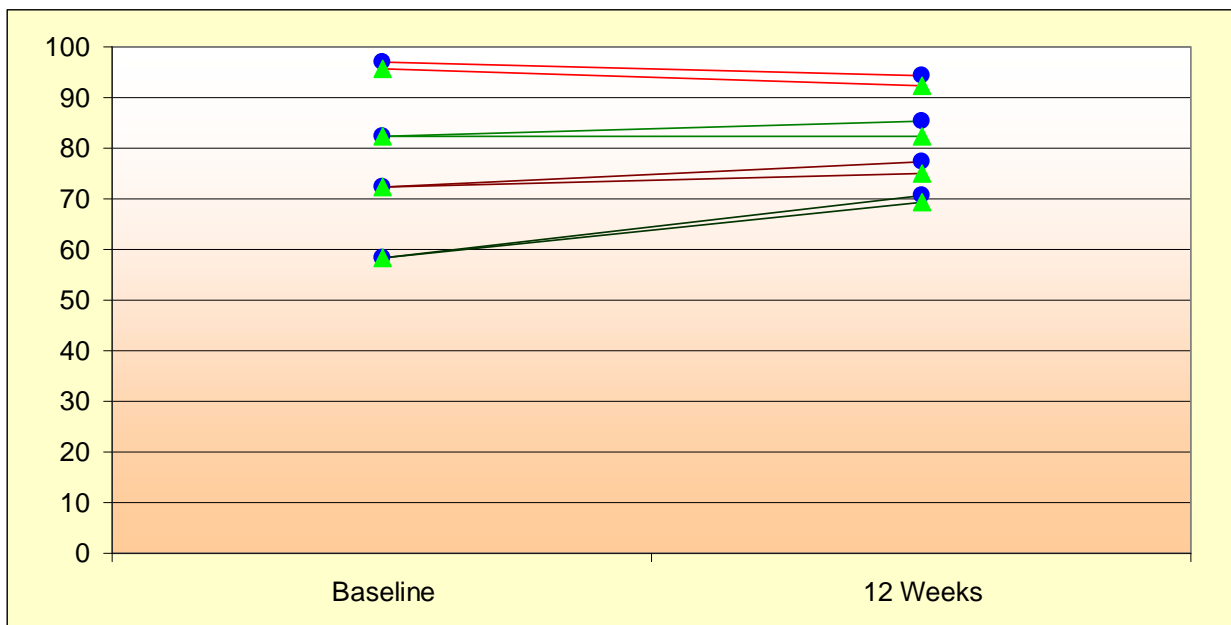


Figure 1. Sit-Up Score by Quartile. No significant Group x Quartile x Time interaction (P=0.543).

Low Back Pain Beliefs Analysis (in review with *Spine*)

The general population has a pessimistic view of LBP and evidence based information has been used to positively influence LBP beliefs in previously reported mass media studies. Since previous studies utilized non-randomized methodologies, there is a lack of randomized trials demonstrating these effects in primary prevention settings.

Companies of Soldiers were recruited into an ongoing clinical trial that had analysis of LBP beliefs as a proximal outcome. Soldiers ($n = 3,792$) were cluster randomized to receive a psychosocial education program (PSEP) or no education (CG). The PSEP consisted of an interactive seminar and Soldiers were issued the *Back Book* for reference material. LBP beliefs were assessed by the Back Beliefs Questionnaire (BBQ) before randomization and 12-weeks later. A linear mixed model was fitted for the BBQ change in continuous scale and a generalized linear mixed model was fitted for the dichotomous outcomes on BBQ change of greater than 2 points. Sensitivity analyses were performed to account for drop out.

BBQ scores (potential range: 9 – 45) improved from baseline of 25.6 ± 5.7 (mean \pm sd) to 26.9 ± 6.2 for those receiving the PSEP, while there was a decline from 26.1 ± 5.7 to 25.6 ± 6.0 for those in the CG. These differences were statistically significant ($p < 0.0001$). The adjusted mean improvement for those receiving the PSEP was 1.74 points higher than those in the CG ($p < 0.0001$). The adjusted odds ratio of BBQ improvement of greater than 2 points for those receiving the PSEP was 1.51 (95% CI = 1.22 – 1.86) times that of those in the CG. BBQ improvement was mildly associated with race, college education, and depression. Sensitivity analyses suggested minimal influence of drop out.

Soldiers that received the PSEP had an improvement in their beliefs related to the inevitable consequences of and ability to cope with LBP.

Table 1 summarizes the key findings from these analyses.

Table 1. Summary of Analyses Results for Low Back Pain Beliefs

Effects	BBQ change (continuous)			BBQ improvement (categorical)			
	Estimate	SE	P-Value	Odds Ratios	95% CI		P-Value
Intercept	0.76	2.70	0.7821				
PSEP	1.74	0.25	<.0001	1.51	1.22	1.86	0.0001
Age	0.04	0.03	0.1629	1.01	0.99	1.03	0.1939
Gender - Female	-0.14	0.27	0.6047	0.90	0.76	1.07	0.2217
Race - Others	-0.40	0.28	0.1505	0.81	0.68	0.96	0.0128
Education - College or more	0.39	0.26	0.1335	1.23	1.05	1.44	0.0106
Income - \$35,000 or more	0.08	0.33	0.8089	1.00	0.82	1.22	0.9722
Time in Army - 1-3 years	0.17	0.63	0.7884	1.11	0.76	1.62	0.5814
Time in Army - < 1 year	-0.22	0.49	0.6553	0.95	0.71	1.27	0.7344
FPQ-III Total at Intake	0.02	0.02	0.2905	1.00	0.99	1.02	0.5859
BDI Total at Intake	-0.06	0.03	0.0453	0.99	0.97	1.01	0.1905
STAI Total at Intake	0.02	0.02	0.4046	1.01	0.99	1.02	0.3146
PCS total at Intake	-0.02	0.03	0.4745	1.00	0.98	1.02	0.9922
MCS total at Intake	-0.04	0.02	0.0788	1.00	0.99	1.01	0.9270

Key: BBQ = Back beliefs questionnaire, PSEP = Psychosocial education program, FPQ-III = Fear of Pain Questionnaire, BDI = Beck Depression Inventory, STAI = State Trait Anxiety Index, PCS = Physical component summary, and MCS = Mental component summary. Continuous outcome was calculated by raw change score and categorical outcome was defined as yes/no depending whether BBQ score increased more than two points from time of intake to follow-up. Statistically significant predictors are indicated in bold.

Mental Health Analysis (in review with *Am J Epidemiol*)

Predictors of mental health (primarily depression) and suicide in military populations have not received adequate research attention. Branches of the military need military-specific information about factors related to anxiety, depression, and suicide. They suggested that viable candidate factors included deployment status, combat stress, alcoholism, and sex/gender. The purpose of this study was to examine mental health symptoms (anxiety, depression, and suicidal ideation) in a sample of soldiers enrolled in combat medic training. The data were collected as part of a longitudinal study examining back pain in the military and offered a relatively unique opportunity to examine the aforementioned mental health symptoms in a longitudinal design.

Depression, anxiety, and suicidal ideation were examined at the beginning and end of the 12-week training. At the start of training, 10.4%, 15.5%, and 4.1% of soldiers had clinically significant depression, anxiety, or suicidal ideation, respectively. These percentages increased to 12.2%, 20.3%, and 5.7% at completion of training. Worsening of depression, anxiety, and suicidal ideation occurred for 7.7%, 11.4% and 4% of soldiers. At both the beginning and end of training, higher percentages of symptoms were associated with females, lower education, and lower income (Table 3). Active duty personnel were more likely to worsen following training with respect to suicidal ideation (OR = 1.9, 95% CI: 1.2-2.9) compared to reservists.

This study represents one of the few prospective, pre-deployment investigations of depression, suicidal ideation, and anxiety in the military. Unique features of the study include the investigation of the change in negative mood associated with training, and the predictors of negative mood and change in mood in a military population. The rising incidence of mental health issues in military personnel, most likely the result of recent conflicts, highlights the need to investigate predisposing factors associated with mental health risk, and the effects of training on mental health symptoms.

Table 2 summarizes the key findings from these analyses.

Table 2. Results of Generalized Linear Mixed Models for the Dichotomous Outcomes on Depression, Anxiety, and Suicidal Ideation

Effects	Intake				Followup				Became Worse			
	Odds Ratio	95% CI	P-Value		Odds Ratio	95% CI	P-Value		Odds Ratio	95% CI	P-Value	
Depression												
Age	0.94	0.91	0.97	0.0002	0.97	0.94	1.01	0.0943	0.99	0.96	1.03	0.7131
Gender – Female	1.73	1.39	2.16	<.0001	1.64	1.30	2.08	<.0001	1.62	1.22	2.15	0.0010
Race - Others	0.85	0.67	1.08	0.1810	0.83	0.64	1.08	0.1630	0.81	0.58	1.12	0.1947
Education - ≥ College	0.89	0.71	1.12	0.3275	0.79	0.62	1.01	0.0628	0.84	0.63	1.13	0.2585
Income - ≥ \$35,000	0.87	0.63	1.18	0.3581	1.11	0.81	1.52	0.5066	1.40	0.98	2.00	0.0643
Time in Army – 1-3 yr	0.47	0.27	0.80	0.0058	1.45	0.77	2.73	0.2464	1.62	0.75	3.47	0.2170
Time in Army < 1 yr	0.52	0.35	0.77	0.0011	1.22	0.72	2.07	0.4604	1.32	0.70	2.52	0.3923
Navy/Air Force – No	0.56	0.32	0.97	0.0401	1.35	0.57	3.16	0.4951	1.96	0.60	6.34	0.2625
Active Duty - Yes	1.02	0.82	1.28	0.8529	1.26	0.99	1.61	0.0566	1.18	0.88	1.58	0.2712
Anxiety												
Age	0.94	0.91	0.97	<.0001	0.97	0.94	1.00	0.0183	0.99	0.96	1.02	0.6044
Gender – Female	1.39	1.15	1.68	0.0008	1.49	1.22	1.81	<.0001	1.36	1.06	1.74	0.0151
Race - Others	0.90	0.74	1.11	0.3252	0.83	0.67	1.02	0.0788	0.78	0.59	1.03	0.0763
Education - ≥ College	0.86	0.71	1.05	0.1347	0.80	0.66	0.98	0.0272	0.87	0.68	1.12	0.2750
Income - ≥ \$35,000	0.96	0.74	1.24	0.7458	0.90	0.69	1.17	0.4354	1.00	0.72	1.38	0.9811
Time in Army – 1-3 yr	0.65	0.41	1.02	0.0610	0.84	0.50	1.41	0.5042	0.71	0.35	1.45	0.3447
Time in Army < 1 yr	0.60	0.42	0.85	0.0043	1.10	0.73	1.65	0.6428	1.34	0.79	2.27	0.2730
Navy/Air Force – No	0.85	0.50	1.45	0.5484	1.01	0.55	1.86	0.9806	0.87	0.43	1.79	0.7082
Active Duty - Yes	1.00	0.82	1.20	0.9573	1.22	1.00	1.48	0.0456	1.19	0.93	1.52	0.1584
Suicidal Ideation												
Age	0.97	0.92	1.02	0.1812	0.96	0.92	1.01	0.1263	0.97	0.92	1.03	0.3135
Gender – Female	1.13	0.80	1.61	0.4863	1.08	0.76	1.52	0.6828	1.06	0.70	1.60	0.7901
Race - Others	1.13	0.79	1.61	0.5040	1.12	0.79	1.60	0.5283	0.99	0.65	1.52	0.9662
Education - ≥ College	1.08	0.76	1.53	0.6736	1.06	0.76	1.50	0.7295	0.99	0.66	1.48	0.9660
Income - ≥ \$35,000	0.70	0.42	1.16	0.1661	0.90	0.56	1.43	0.6396	1.14	0.68	1.92	0.6278
Time in Army – 1-3 yr	1.82	0.76	4.34	0.1775	2.71	0.96	7.64	0.0596	1.52	0.44	5.30	0.5125
Time in Army < 1 yr	1.10	0.52	2.32	0.8127	2.04	0.81	5.11	0.1307	1.89	0.67	5.31	0.2264
Navy/Air Force – No	1.03	0.37	2.88	0.9585	0.58	0.24	1.39	0.2236	0.65	0.23	1.87	0.4222
Active Duty - Yes	0.99	0.70	1.39	0.9567	1.57	1.11	2.22	0.0113	1.90	1.24	2.92	0.0034

KEY RESEARCH ACCOMPLISHMENTS

- Performance on the Army Physical Fitness Test (APFT) was not affected by performing the core stabilization exercise program (CSEP) utilized in this study. In fact, slightly higher passing rates were observed on the sit up portion of the APFT for Soldiers completing the CSEP.
- The psychosocial education program (PSEP) effectively improved Soldiers beliefs on the management of and ability to cope with low back pain (LBP). The size of improvement in LBP beliefs was comparable to other studies reported in Australia, Norway, and Scotland. This is the first time improvement in LBP beliefs has been reported from a clinical trial and also represents the first time these data have been reported from the United States.
- Worsening of depression, anxiety, and suicidal ideation occurred during advanced individual training (AIT) of combat medics. Specifically, sex, income, education, and reserve status were significant predictors of mental health status and these data may serve a practical purpose to aid in identification of individuals at risk for worsening mental health before deployment.

REPORTABLE OUTCOMES

- Papers in press

George SZ, Childs JD, Teyhen DS, Wu SS, Wright AC, Dugan JL, Robinson ME. Rationale, design, and protocol for the prevention of low back pain in the military (POLM) trial (NCT00373009). *BMC Musculoskelet Disord*, 2007;8:92.

- Papers in review

Childs JD, George SZ, Wright AC, Dugan JL, Benedict T, Fortenberry A, Bush J, Preston J, McQueen R, Teyhen DS. The Effects of Traditional Sit-Up Training Versus Core Stabilization Exercises on Sit-Up Performance in US Army Soldiers: A Cluster Randomized Trial (NCT00373009). *Med Sci Sports Exerc*, in review.

George SZ, Teyhen DS, Wu SS, Wright AC, Dugan JL, Yang G, Robinson ME, Childs JD. Psychosocial education improves low back pain beliefs: results from a cluster randomized clinical trial (NCT00373009). *Spine*, in review.

Robinson ME, Teyhen DS, Wu SS, Dugan JL, Wright AC, Yang G, Childs JD, George SZ. Mental health symptoms in combat medic training: a longitudinal examination. *Am J Epidemiol*, in review.

- Published abstracts

George SZ, Childs JD, Teyhen DS, Wu SS, Wright AC, Dugan JL, and Robinson ME. Rationale, design, and protocol for the prevention of low back pain in the military (polm) trial (NCT00373009). *Proceedings of the 10th Annual Force Health Protection Conference*, abstracted 2007.

CONCLUSION

Overall

The POLM trial continued to be a tremendous success in its second year. The research team was able to complete all Year 2 tasks in a timely fashion, and Year 3 tasks related to dissemination of early analyses were initiated. Recruitment has been completed, with over 4,000 Soldiers successfully enrolled in the trial. Follow-up assessment will continue in Years 3 and 4, with the immediate follow-up testing occurring at a high rate, but with substantially lower rates noted in the long term follow-up testing. Continued success of the POLM trial involves improving low follow up rates, which will be a priority for the research team in Year 3.

So far, data from the trial provide encouraging results from the implemented programs. First, it does not appear that performance of the core stabilization exercise program adversely affects performance on the Army Physical Fitness Test. Second, the education program implemented in the study effectively improved Soldier beliefs about low back pain. Third, we have reported potential factors associated with worsening of mental health status during training.

So What?

The POLM trial is still 2 years away from reporting on its primary outcomes of low back pain occurrence and severity. However, preliminary analyses have provided promising information on the exercise and education interventions used in the trial. We have also reported on risk factors of poor mental health, an important topic in the military. These data will be the focus of early dissemination as we continue to monitor episodes of LBP over the next 2 years.

REFERENCES

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APPENDICES

None